IN THE CIRCUIT COURT OF DREW COUNTY, ARKANSAS
CIVIL DIVISION

DREW MEMORIAL HOSPITAL, INC — PLAINTIFF

vs. Case No. CV-2017-221-3

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS
PHARMA, INC.; f/k/a WATSON PHARMA, INC.; AMERISOURCEBERGEN
DRUG CORPORATION; CARDINAL HEALTH, INC.;
McKESSON CORPORATION; DR. RICHARD JOHNS;
& JOHN DOE DEFENDANTS 1 THROUGH 9 — DEFENDANTS

Filed For Record
Drew County, AR
Beverly Burks, Circuit Clerk
By: VOID
DEC 14 2017
(A)M1/2/3/4/5/6/7/8/9/10/11/12PM

CLASS ACTION COMPLAINT

TABLE OF CONTENTS

		Page
I.	INTRODUCTION	3
II.	JURISDICTION AND VENUE	7
III.	PARTIES	7
	A. Plaintiff	7
	B. Defendants	7
IV.	FACTUAL ALLEGATIONS	11
	A. Defendants used Multiple Avenues to Disseminate their Fales and Deceptive Statements about Opioids	12
	1. Defendants spread and continue to spread false and deceptive statements through marketing opioids	12
	2. Defendants used third parties to spread false and	

Deceptive statements about risks of opioids.....15

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.....26
1. Defendants falsely trivialized or failed to disclose the known risks of opioid use.....27
2. Defendants grossly overstated the benefits of Chronic opioid therapy.....37
3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.....41

C. Defendants Targeted Susceptible Prescribers & Vulnerable Patient Populations.....44

D. Defendants Knew their Marketing of Opioids was False and Deceptive and Fraudulently Concealed their Misconduct.....45

E. Defendants Misconduct Fueled the Opioid Crisis & Caused Plaintiff to Suffer Substantial damages.....46

F. Defendants' Fraudulent Marketing Led to Record Profits.....50

G. Wholesale Distributor Defendants: The First Line of Defense.....50

V. PLAINTIFF'S CLASS ACTION CLAIMS.....52

VI. CAUSES OF ACTION.....54

1. Negligence.....54

2. Strict Product Liability: Ark. Code Ann. § 16-116-102(a).....56

3. Drug Dealer Liability Act: Ark. Code Ann. § 16-124-104.....57

VII. JURY DEMAND.....58

VII. PRAYER FOR RELIEF.....58

Plaintiff, DREW MEMORIAL HOSPITAL, INC. by and through its attorneys, Mann & Kemp, PLLC, The Edwards Firm, PLLC and Gibson & Keith, PLLC, on behalf of itself and all others similarly situated, brings this class action lawsuit against Defendants and states as follows:

I. INTRODUCTION

1. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

2. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the State of Arkansas.

3. Defendants manufacture, market, distribute, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin and Percocet, and genetic drugs like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for treatment of chronic pain (like back pain, migraines, and arthritis), opioids were used only to treat short-term acute pain or for palliative (end of life) care.

4. But by the late 1990s, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that opioids can be used effectively for treatment of chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from long-term use of opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using opioids to treat chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to

the language of their drugs' labels: (1) downplayed the serious risk of addition; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

5. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages. Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

6. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use and continues to fail to correct its past misrepresentations.

7. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain." This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

8. It is hardly necessary to say—in this County or this State—that Arkansas is now awash in opioids and engulfed in a public health crisis the likes of which have been seen before. In

2016, the total number of opioid doses prescribed to Arkansas patients soared to 235.9 million – ***enough to supply every man, woman and child in the state with 80 pills each.***

9. The result of Arkansas's opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years. But even these alarming statistics do not fully illustrate the toll of prescription opioid use on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long-term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients by physicians like Defendant Richard Johns, who is currently incarcerated in the federal prison in Leavenworth, Kansas, for operating an opioid "pill mill." Dr. Johns pled guilty to federal charges for selling thousands of opioid prescriptions.

10. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in the use of heroin, imposing additional burdens on the state's hospitals addressing opioid abuse. Individuals who become addicted to prescription opioids often transition to heroin and other opioids because they are less expensive and a readily available alternative that provides a similar "high."

11. Defendants' conduct has also exacted, and foreseeably so, a financial burden on hospitals in the State of Arkansas, including uncompensated treatment of opioid overdoses, long-term treatment for addiction to prescription opioids, treatment for other opioid related injuries, and treatment of babies born addicted to opioids as a result of their mothers' abusing the drugs.

12. To redress and punish these violations of law, Drew Memorial Hospital brings this class action lawsuit against Defendants on behalf of itself and every other hospital in Arkansas,

excluding those hospitals operated by the state or federal government, to recover compensatory and punitive damages.

II. JURISDICTION & VENUE

13. This Court has jurisdiction over the subject matter and parties to this action, and venue is proper in this Court.

III. PARTIES

14. Plaintiff Drew Memorial Hospital, Inc. is a non-profit corporation organized under the laws of the State of Arkansas with its principal place of business in Monticello, Arkansas. Plaintiff is a regional healthcare provider located in Drew County, Arkansas. Plaintiff has provided uncompensated care and treatment for those who suffer in the prescription opioid crisis. Plaintiff brings this action on behalf of itself and all other hospitals in the State of Arkansas, excluding those hospitals owned and operated by the state and federal governments.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Arkansas. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

17. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware

corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

18. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Arkansas. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

19. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Arkansas, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva USA's logo. (Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. are collectively referred to herein as "Cephalon.").

20. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than

10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.")

21. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Arkansas, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

22. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

23. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Arkansas. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Arkansas.

24. WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC.

ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. (Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."). Activis Pharma, Inc. may be served with process through its registered agent: Corporate Creations Network, Inc., 609 S.W. 8th Street, Suite 1900, Bentonville, Arkansas 72712.

25. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Arkansas. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

26. Defendant AMERISOURCEBERGEN DRUG CORPORATION is registered with the Arkansas Secretary of State as a foreign for-profit corporation which may be served through its registered agent: The Corporation Company, 124 West Capitol Avenue, Suite 1900, Little Rock, Arkansas 72201. AMERISOURCEBERGEN DRUG CORPORATION'S principal place of business located in Chesterbrook, Pennsylvania, and is in the business of distributing opioids in the U.S. and Arkansas.

27. Defendant CARDINAL HEALTH, INC. is an Ohio for-profit corporation with its principal place of business located in Dublin, Ohio, and is in the business of distribution opioids in the U.S. and Arkansas.

28. Defendant McKESSON CORPORATION, is a foreign for-profit corporation which may be served through its registered agent: Corporation Service Company, 300 Spring Building, Suite 900, 300 Spring Street, Little Rock, Arkansas 72201. McKesson Corporation has its principal place of business located in San Francisco, California. McKesson is in the business of distribution of opioids in the U.S. and Arkansas.

29. Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The PurdueFrederick Company, Inc.; TEVA Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen

Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janseen Pharmaceuticals, Inc. Endo Health Solutions, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Activas Pharma, Inc. f/k/a Watson Pharma, Inc. were at all times pertinent to this Complaint in the business of designing, manufacturing, marketing, and selling opioids in the United States and Arkansas and are hereinafter referred to as the "Manufacturing Defendants."

30. Defendants AmeriscourceBergen Drug Corporation; Cardinal Health, Inc.; and McKesson Corporation were at all times pertinent to this Complaint in the business of distributing opioids in the United States and Arkansas and are hereinafter referred to as the "Distributing Defendants."

31. Defendant Dr. Richard Johns is a resident of the State of Arkansas with his principal residence located at 5600 Ridgefield Laue, Little Rock, Arkansas 72223. Dr. Johns is currently incarcerated in federal prison after pleading guilty to federal charges of selling opioid drug prescriptions. It is believed that Dr. Johns sold thousands of pills out of his medical practices in Pulaski, Lonoke, and White Counties.

32. The identities of additional John Doe Defendants 1 through 9 are unknown at the time of the filing of this Class Action Complaint.

IV. FACTUAL ALLEGATIONS

33. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

34. To take advantage of the lucrative market for chronic pain patients, the Defendants developed a well-funded marketing scheme based on deception. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use—statements that benefited not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Defendants Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids

35. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Arkansas. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State of Arkansas.

1. Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

36. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

37. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-

term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

38. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

39. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

40. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs

provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

41. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturing Defendants *know* their detailing to doctors is effective.

42. Defendants employed the same marketing plans and strategies and deployed the same messages in Arkansas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

43. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker

slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

44. Defendants also deceptively marketed opioids in Arkansas through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

45. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

46. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids as **prescribed usually do not become addicted.**"	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use.**"

a. Key Opinion Leaders ("KOLs")

47. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

48. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

49. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then

cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

50. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

51. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

52. Thus, even though some of Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Arkansas in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

53. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

i. Russell Portenoy

54. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

55. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

56. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Arkansas and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

57. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portnoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain

management, specifically about therapy, in a way that reflects misinformation? Well, ... I guess I did."

ii. Lynn Webster

58. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

59. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

60. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

61. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Arkansas doctors. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."

b. Front Groups

62. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

63. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups

by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants ensured that the Groups would generated only the messages Defendants wanted distributed. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

64. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

65. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

66. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Arkansans.

67. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

68. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

69. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

70. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

71. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

72. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

73. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

74. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

75. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

76. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

77. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."

78. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

79. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

80. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

81. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

82. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Arkansas during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

83. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

84. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing.

B. Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.

85. To convince doctors and patients in Arkansas that opioids can and should be used to treat chronic pain, the Manufacturing Defendants had to convince them that long-term opioid

use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, the Manufacturing Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Manufacturing Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Manufacturing Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

86. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

87. First, the Manufacturing Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained

illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon in Arkansas minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

88. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

89. The FDA further exposed the falsity of the Manufacturing Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

90. The warnings on the Manufacturing Defendants' own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

91. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.

92. Second, the Manufacturing Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturing Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

93. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

94. Every one of the Manufacturing Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing

"between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

95. Third, the Manufacturing Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturing Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturing Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

96. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill

counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

97. Fourth, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

98. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

99. The Manufacturing Defendants deceptively minimized the significant symptoms of opioid withdrawal– which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on

opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

100. Fifth, the Manufacturing Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturing Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked

"If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

101. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

102. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

103. Finally, the Manufacturing Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

104. More specifically, the Manufacturing Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

105. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

106. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

2. Manufacturing Defendants grossly overstated the benefits of chronic opioid therapy.

107. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, the Manufacturing Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturing Defendants failed to correct these false and deceptive claims, they continue to make them today.

108. For example, the Manufacturing Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like

construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which

claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

109. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

> "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
>
> "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
>
> "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

110. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

111. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturing Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side

effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

112. The Manufacturing Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

113. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that

a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

114. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Arkansas doctors that OxyContin lasts a full 12 hours.

115. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleeps though the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.

3. The Manufacturing Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.

116. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve

Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

117. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

> Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.
>
> Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
>
> In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain"
> – and not just cancer pain.

118. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

119. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.

120. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers like Dr. Richard Johns; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

121. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

122. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State

of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. The Manufacturing Defendants Targeted Susceptible Prescribers & Vulnerable Patient Populations.

123. As a part of their deceptive marketing scheme, the Manufacturing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Arkansas. For example, the Manufacturing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

124. The Manufacturing Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. Although the Manufacturing Defendants Knew that their Marketing of Opioids Was False & Deceptive, They Fraudulently Concealed Their Misconduct.

125. The Manufacturing Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturing Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

126. Moreover, at all times relevant to this Complaint, the Manufacturing Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturing Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturing Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. The Manufacturing Defendants also never disclosed their role in shaping, editing, and approving the content of information and

materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involveinent. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

127. Finally, the Manufacturing Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Manufacturing Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff.

128. Manufacturing Defendants successfully concealed from the medical community, patients, and healthcare payers the facts sufficient to arouse suspicion of the claims that the Hospitals now assert. The statute of limitations was therefore tolled pursuant to Ark. Code Ann. § 16-56-120.

E. By Increasing Opioid Prescriptions & Use, Defendants' Deceptive Marketing Scheme Has Fueled the Opioid Epidemic & Caused Plaintiff Substantial Damages.

129. The Manufacturing Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported

in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

130. The Manufacturing Defendants' deceptive marketing scheme caused and continues to cause doctors in Arkansas to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

131. The Manufacturing Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturing Defendants' spending on their deceptive marketing scheme. The Manufacturing Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

132. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturing Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arkansas. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . .

[m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

133. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

134. Contrary to the Manufacturing Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

135. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Arkansas, which ranks fourth in the country in pill prescribed according to the Centers for Disease Control.

136. The overprescribing of opioids for chronic pain caused by the Manufacturing Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arkansas who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw.

137. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed the Plaintiff Hospital.

138. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals.

139. The Manufacturing Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. The Manufacturing Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

140. The Manufacturing Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

141. Nor is the Manufacturing Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive

messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

F. Defendants' Fraudulent Marketing Has Led To Record Profits.

142. While the use of opioids has taken an enormous toll on the Plaintiff, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturing Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

G. Wholesale Distributor Defendants: The First Line of Defense

143. Separate Defendants AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; AND McKESSON CORPORATION (hereinafter the "Wholesale Distributor Defendants"). The Wholesale Distributor Defendants are in the chain of distribution of prescription opioids, chiefly hydrocodone and oxycodone.

144. In 1970, Congress devised a "closed" chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illegal drug market. 21 U.S.C. § 801(2); 212 U.S.C. §§ 821–824, 827, 880. This closed system imposes specific duties on wholesale distributors to monitor, identify, halt, and report "suspicious orders" of controlled substances like prescription opioids. 21 C.F.R. § 1301.74(b) ("Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."). Under federal law, Wholesale Distributor Defendants were intended to be the first line of defense in the opioid crises.

145. Defendant Wholesale Distributors owe a duty under federal law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids.

146. According to the DEA, the Wholesale Distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."

147. Each Wholesale Distributor had an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C.A. §§ 823(b)(1).

148. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

149. Opioid prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous. 1970 U.S.C.C.A.N. 4566, 4571–72.

150. Upon information and belief, the Wholesale Distributors failed to report to the DEA "suspicious orders" originating from Arkansas, including orders shipped pursuant to prescriptions written by Separate Defendant Richard Johns. The Wholesale Distributor Defendants likewise failed to report orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Arkansas.

151. Plaintiff alleges that the Defendant Wholesale Distributors unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency, including those prescriptions issued by Defendant Richard Johns.

152. Each Defendant Wholesale Distributor breached its duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

153. Each Defendant Wholesale Distributor breached its duty to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of federal law. 21 CFR § 1301.74(b).

154. Each Defendant Wholesale Distributor breached its duty to design and operate a system to disclose suspicious orders of controlled substances and failed to inform the DEA of "suspicious orders for drugs when discovered" in violation of 21 CFR § 1301.74(b).

155. Defendant Wholesale Distributors' violations of federal law amounts to evidence of their negligence. AMI-Civil 601.

V. CLASS ACTION CLAIMS

156. Plaintiff brings this action individually and in a representative capacity pursuant to Arkansas Rule of Civil Procedure 23 against the Defendants pleading claims of common law negligence and statutory claims of strict product liability and the Drug Dealer Liability Act, on

behalf of the following class: all hospitals in the State of Arkansas, specifically excluding all hospitals owned or operated by the State of Arkansas.

157. The class plaintiffs are so numerous that joinder of all individual claims is impracticable. Upon information and belief, the class consists of approximately 90 separate facilities throughout the State of Arkansas serving various populations from rural communities to more prosperous urban settings. The opioid crisis set in motion by Defendants' wrongful conduct is truly as statewide phenomenon.

158. Specifically excluded from the putative Plaintiff Class are hospitals owned or operated by the state or federal government.

159. There are questions of law and fact common to the Plaintiff Class which predominate questions affecting only individual class members. Such common questions include, but are not limited to

a. Whether Defendants violated Food and Drug Administration regulations, including regulations governing promotion and marketing of prescription drugs.

b. Whether Defendants adequately warned of the dangers posed by opioid use for treatment of chronic pain.

c. Whether Defendants' opioids were supplied to the end user in a defect condition that rendered the drug unreasonably dangerous.

d. Whether the drug's defective condition was a proximate cause to Plaintiff's damages.

e. Defendants knowingly participated in the chain of distribution of an illegal drug or participated in the illegal drug market at any time during the illegal drug use of an individual drug user.

f. Whether Defendants knowingly turned a blind eye to suspicious orders of opioid prescription drugs.

160. The Plaintiff will fairly and adequately protect the interest of the Plaintiff Class and has familiarity with the allegations expressed herein and is able to assist in decision making as to the conduct of the litigation.

161. Plaintiff's claims are typical of the claims of the class because the class representative's claims arise from the Defendants' nation-wide scheme to promote the sale of opioid drugs that ultimately led to the uncompensated care and treatment necessarily provided by the Plaintiff Class.

162. Plaintiff has retained counsel qualified, experienced and able to conduct the litigation, and Plaintiff has made arrangements to cover the costs associated with this litigation.

163. If each class member were required to pursue individual actions, it would be economically and judicially unfeasible. A class action is appropriate and the superior method for the fair and efficient adjudication of this controversy.

VII. CAUSES OF ACTION

COUNT ONE: NEGLIGENCE AGAINST ALL DEFENDANTS

164. Plaintiff incorporates the allegations contained in Paragraphs 1–163 as if fully set forth herein.

165. The Manufacturing Defendants, the Wholesale Distributor Defendants, and Richard Johns owed a duty to use ordinary care, or that care that a reasonable person would use under circumstances similar to those shown by the evidence. Defendants general duty owed to Plaintiff rests upon Defendants activities manufacturing, marketing, distributing, and selling opioids in the State of Arkansas.

166. In manufacturing, marketing, distributing and selling opioids, a highly dangerous and addictive drug, Defendants had a duty to act as a reasonable person and take precautions to avoid unreasonable risks and injury to others, including the Plaintiff Class.

167. A reasonably prudent manufacturer, distributor, and prescribing physician would have, or should have, anticipated the scourge of opioid addition and that it would wreak havoc on communities and leave healthcare provides holding the bill for providing lifesaving and expensive care for those who became addicted to Defendants' drugs.

168. Defendants breached the duty they owed to Plaintiff as outlined above and incorporated herein by failing to warn of the significant risks posed by prescription opioids, by failing to warn physicians and the public of the risks of addiction, by turning a blind eye to known suspicious orders of prescription opioids, by failing to report known pill mills, among others.

169. Defendants' breach of the duty they owed to Plaintiff resulted in foreseeable damages. Plaintiff provided uncompensated care and treatment to those injured as a result of the prescription opioid crisis.

170. As a direct and proximate result of such grossly negligent, willful, wanton, reckless, malicious and/or intentional conduct, Plaintiff asserts a claim for judgment for all compensatory and punitive damages against the Defendants including, but not limited to, uncompensated care and treatment of those who became addicted to Defendants' drugs and those individuals injured in the drug trade in an amount exceeding that required by federal court jurisdiction in diversity of citizenship cases, to be determined by the jury, plus costs and all other relief to which Plaintiff is entitled by law.

171. The Plaintiffs are also entitled to punitive damages as the defendants knew or should have known, in light of the surrounding circumstances, that their actions would naturally and probably result in injury or damage, yet the Defendants acted in reckless disregard of the consequences from which malice may be inferred.

COUNT TWO: STRICT PRODUCT LIABILITY

172. Plaintiff incorporates the allegations contained in Paragraphs 1–171 as if fully set forth herein.

173. At all times pertinent to this cause of action, the Defendants were engaged in the business of manufacturing, assembling, selling, and distributing opioids.

174. At the time that the Defendants manufactured and sold the drugs, the opioids contained defects in its design that made it unreasonably dangerous and unfit for its intended use. These defects include, but are not limited to, defect in design, defect in the manufacturing process, defect in marketing by improper, inadequate instructions, and failure to warn of the dangers of the product. Notwithstanding the Defendants' claims of the safety of the drug and that it was not addictive, it is now clear that opioids are highly addictive, incredibly destructive, and unreasonably dangerous. The design defect proximately caused injury and damages to Plaintiff and Plaintiff's property. The design defect in opioids rendered the product dangerous to an extent beyond that which would be contemplated by the ordinary and reasonable buyer of the drug.

175. The Defendants are strictly liable for the injuries suffered by Plaintiff caused by the design defect in opioids. Plaintiff's injuries and losses are continuing and permanent in nature.

176. As a direct and proximate result of the defective design of opioids, Plaintiff asserts a claim for strict liability against the Defendants. Plaintiff prays for a judgment for all compensatory and punitive damages against Defendants including, but not limited to, uncompensated care and treatment of those who became addicted to Defendants' drugs and those individuals injured in the drug trade, and related expenses, including any such damages reasonably certain to be incurred in the future, in an amount exceeding that required by federal court

jurisdiction in diversity of citizenship cases to be determined by the jury, plus costs and all other relief to which Plaintiff is entitled by law.

COUNT THREE: ARKANSAS DRUG DEALER LIABILITY ACT

177. Plaintiff incorporates the allegations contained in Paragraphs 1–176 as if fully set forth herein.

178. The Arkansas Drug Dealer Liability Act, ("ADDLA"), Ark. Code Ann. § 16-124-101 et. seq. provides a civil remedy for those injured by the illegal drug trade.

179. A medical care facility like Plaintiff is a "person" who "may bring an action in circuit court for damages caused by use of an illegal drug. Ark. Code Ann. § 16-124-104(a).

180. Under Arkansas criminal laws, opioids are illegal drugs for purposes of the ADDLA. By default, it is illegal to possess any Schedule II drug, including opioids. Ark. Code Ann. § 5-64-419. Possession of opioids only becomes legal once prescribed to an individual by a physician in compliance with federal law. Ark. Code Ann. § 5-64-308.

181. The ADDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damages. A medical facility like Plaintiff is entitled to bring a claim under the ADDLA against any "person who knowingly distributed, or knowingly participated in the distribution of an illegal drug that was actually used by the individual drug user." Ark. Code Ann. § 16-124-104(b).

182. Under the ADDLA, a medical care facility like Plaintiff may recover all of the following damages:

(1) Economic damages, including, but not limited to:

A. The costs of treatment and rehabilitation;

B. Medical Expenses;

C. Loss of economic or educational potential;

D. Loss of productivity;

C. Absenteeism;

F. Support expenses;

G. Accidents or injury; and

H. Any other pecuniary loss caused by the illegal drug use;

(2) Exemplary damages;

(3) Reasonable attorney's fees;

(4) The costs of suit, including, but not limited to, reasonable expenses for expert testimony.

Ark. Code Ann. § 16-124-104(c).

183. Plaintiff asserts a claim under the ADDLA for judgment for all compensatory and punitive damages against the Defendants including, but not limited to economic damages, exemplary damages, reasonable attorney's fees; and the costs of bringing this suit, including but not limited to, expert witness fees, in an amount exceeding that required by federal court jurisdiction in diversity of citizenship cases, to be determined by the jury, plus costs and all other relief to which Plaintiff is entitled by law.

DEMAND FOR JURY TRIAL

184. Plaintiffs and the Plaintiff Class demand trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs and the Plaintiff Class pray for the following relief:

a. For certification of a class consisting of all hospitals in the State of Arkansas, excluding those owned and operated by the state and federal governments;

b. Appointment of Plaintiff as representative of the Class;

c. Appointment of Plaintiff's counsel as attorneys for the Class;

d. For judgment against all Defendants for actual damages, compensatory damages, exemplary, and punitive damages.

e. Attorney's fees and all costs incurred in the prosecution of this action and for all other appropriate relief.

Respectfully submitted.

Joseph Hamilton Kemp, Ark. Bar No. 2008283
Mann & Kemp, PLLC
221 West Second Street, Suite 408
Little Rock, Arkansas 72201
hamilton@mannkemp.com

Robert Henry "Bob" Edwards, Ark. Bar No. 99010
The Edwards Firm, P.L.L.C.
711 West Third Street
Little Rock, Arkansas 72201
bob@bobedwardslaw.com

C.C. "Cliff" Gibson, III, Ark Bar No. 81067
Lee Douglas Curry, Ark Bar No. 2014153
Gibson & Keith, P.L.L.C.
119 South Main Street
P.O. Drawer 447
Monticello, AR 71657
ccgiii@gibsonandkeith.com
ldc@gibsonandkeith.com

Attorneys for the Plaintiff